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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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MYERS DAWES ANDRAS & SHERMAN, LLP
19900 MACARTHUR BLVD.,
SUITE 1150
IRVINE, CA 92612

EXAMINER	
TOWA, RENE T	

ART UNIT	PAPER NUMBER
3736	

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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/763,540	LI ET AL.	
	Examiner	Art Unit	
	Rene Towa	3736	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *30 May 2007*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1,8,13,19 and 45-65* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1,8,13,19 and 45-65* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

1. This Office action is responsive to an amendment filed May 30, 2007. Claims 1, 8, 13, 19 & 45-65 are pending. Claims 1, 8, 13 & 19 have been amended. Claims 2-7, 9-12, 14-15, 17-18 & 20-44 have been cancelled. New claims 45-65 have been added.

Claim Objections

2. Claims 1, 8, 13, 19 & 45-65 are objected to because of the following informalities:

In regards to claim 1, at lines 11-12, the phrase "the base unit for selectively providing medical diagnosis and/or treatment related to the oral sample" renders the claim indefinite; for example, the phrase appears to be lacking a verb.

In regards to claim 13, at lines 9-10, the phrase "as an integral unit as a plurality of lollipops" renders the claim indefinite; it appears that the applicant intends to claim a step of providing a plurality of lollipop-like assemblies, which individually integrate a platform, microchip and stick together.

In regards to claim 19, at line 10, the limitations "based unit" should apparently read --base unit--.

In regards to claim 45, at line 8, insert --wherein-- between "assemblies" and "the base."

In regards to claim 54, at line 3, the limitations "different thicknesses" render the claim indefinite; for example, at line 1, the claim refers to a single coating but later mentions "different thicknesses." As such, it is unclear whether or not the system comprises a single or a plurality of coatings of "different thicknesses."

In regards to claim 60, at line 2, the limitations "biometrics" should apparently read --biometric-- to avoid a potential lack of antecedent basis.

In regards to claim 63, at line 1, insert --is-- between "device" and "used" to avoid a potential indefiniteness problem.

Appropriate correction is required.

Claim Rejections - 35 USC § 103

3. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

"A system" hereinafter is intended to mean "an apparatus" and/or "a method."

4. Claims 1, 13, 19, 45-51, 54-57 & 62-65 are rejected under 35 U.S.C. 103(a) as being unpatentable over Kuo (US 6,623,698) in view of Giuliani et al. (US 5,476,384), Murayama (US Re. 36,699), and Doneen et al. (US 6,102,872).

***In regards to claims 1, 13, 19 & 45-48, 50, 56, 62-65**, Kuo discloses a system for making a physiological test comprising:*

a biometric device for collecting and analyzing the oral fluid;

an oral platform or device 6;

a microchip (i.e. matrix of sensors 138, 140) mounted on or in the platform 6 for making medical diagnoses;

a stick 2 connected to the platform 6 to serve as a handle and electrical conduit to and from the microchip and the platform 6, where the platform, microchip, and stick are mechanically combined together; and

a base unit 2 for providing a medical diagnosis related to the oral sample (see figs. 1a, 4a-c & 5a-c; column 6/lines 32-54 & 60-67; column 7/lines 1-20; column 8/lines 53-63; column 9/lines 32-50; column 10/lines 25-31; column 14/lines 37-41; column 16/lines 40-53);

wherein the biometric device as controlled by the base unit 2 performs a colorimetric or electrochemical bioassay (see column 16/lines 47-53) that monitors physical phenomena including oral activity;

wherein the system further comprises means for delivering drugs (see fig. 6A; column 10/lines 25-27; column 37-41);

wherein the system also comprises means for inducing a physical change in a patient (see column 9/lines 11-12);

wherein the biometric device performs diagnostics (see abstract);

wherein the biometric device is configured for sustained data collection of oral fluid with patient acceptance and simplicity of application;

wherein the biometric device is configured to test for the presence of a secondary agent (i.e. a blood glucose level, which corresponds to a correct dosage of insulin for a diabetes patient) (see column 6/lines 32-44);

wherein the biometric device is capable of being used to detect analytes related to tooth decay or periodontal disease (i.e. by providing the appropriate reagent cartridge) (see column 6/lines 11-20 & 39-44).

The limitation "stick" is herein construed as "something slender and often cylindrical" as per is Webster's II New Riverside University Dictionary (1994).

Kuo discloses a system, as described above, that fails to explicitly teach an interchangeable base unit, a stick capable of serving as a fluidic conduit, or a combination of an oral platform, biometric device and handle that comprises a lollipop-like assembly.

However, Giuliani et al. disclose a system comprising a stick 13 capable of serving as a fluidic conduit via means 32 for delivering drugs (see figs. 1 & 3; column 2/lines 34-46; column 3/lines 31-49; column 3/line 63 to column 4/line 1; column 6/lines 13-26; see abstract); wherein the means for delivering drugs is controlled to provide timed drug delivery (see column 5/lines 29-44).

Murayama discloses a system comprising an active cooperative base unit 14 capable of selective and interchangeable communication with a plurality of oral devices (see figs. 2A-B & 4A-B; column 4/lines 16-26; column 5/lines 20-32; column 6/lines 64-67; column 7/lines 1-3).

Doneen et al. disclose a system for making a physiological test comprising a biometric device, an oral platform or device 10', and a stick or handle 26 such that the combination of the oral platform 10', biometric device and handle 26 comprises a lollipop-like assembly; (see figs. 1-3; column 2/lines 33-47; column 3/lines 44-56; column 5/lines 35-44; column 6/lines 17-21; column 7/lines 31-33 & 40-54); wherein the system further includes a filter 12 and preservation means 16 (i.e. citric acid) for preserving the saliva, where the saliva passes through the filter and is combined with preservatives by the preservation means 16 during collection (see column 4/lines 54-64; column 5/lines 9-16, 21-24, 35-38 & 44-50).

Applying the factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) and are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

In regards to claims 1, 13, 19 & 45-48, 50, 56, 62-65:

Since Kuo and Giuliani et al. teach electronic powered brushes with dispensing means (see Kuo, column 10/lines 25-27 & 36-39; column 14/lines 37-41; see Giuliani et al., column 2/lines 34-46), it would have been obvious to one of ordinary skill in the art at the time Applicant's invention was made to provide a system similar to that of Kuo with a stick serving as a fluidic conduit similar to that of Giuliani et al. since such a modification will serve the same purpose of dispensing fluid (see Giuliani et al., column 3/lines 63 to column 4/line 1).

Kuo, Giuliani et al., and Murayama all disclose electronic powered brushes; moreover, Kuo teaches that, as an oral device, the bristle elements can be replaced by a gum massaging element, a dental floss, a toothpick, a tongue scraper or element used for dental or medical functions (see column 16/lines 39-43). As such, it would have been obvious to one of ordinary skill in the art at the time Applicant's invention was made to provide a system similar Kuo as modified by Giuliani et al., above, with an interchangeable base unit similar to that of Murayama in order to preserve the electrical

components of the system while replacing the other elements used for dental functions so as to thereby avoid the spread of an infection.

Since Doneen et al. and Kuo as modified by Giuliani et al. and Murayama, above, teach a system for making a physiological oral test that includes an oral platform, a biometric device and handle as an integral element, it would have been obvious to one of ordinary skill in the art at the time Applicant's invention was made to provide a system similar to that of Kuo as modified by Giuliani et al. and Murayama with an oral platform, a biometric device and handle that are integral in a lollipop-like assembly similar to that of Doneen et al. in order to encourage children to keep the testing device in their mouths and reduce the anxiety associated with oral examinations.

In regards to claims 49:

Doneen et al. and Kuo as modified by Giuliani et al. and Murayama, teach a system for making a physiological oral test that includes an oral platform, a biometric device and handle as an integral element, it would have been obvious to one of ordinary skill in the art at the time Applicant's invention was made to provide a system similar to that of Kuo as modified by Giuliani et al. and Murayama with a filter similar to that of Doneen et al. in order to obtain an ultrafiltered, uniform, non-viscous sample required for accurate measurement (see Doneen et al., column 5/lines 9-16).

In regards to claim 51:

Since Kuo and Giuliani et al. teach electronic powered brushes with dispensing means (see Kuo, column 10/lines 25-27 & 36-39; column 14/lines 37-41; see Giuliani et al., column 2/lines 34-46), it would have been obvious to one of ordinary skill in the art

at the time Applicant's invention was made to provide a system similar to that of Kuo with a timed drug delivery means similar to that of Giuliani et al. in order to controllably deliver the drug so that no drug is dispensed when the oral device is not in use.

In regards to claim 54:

Kuo as modified by Giuliani et al., Murayama and Doneen et al. disclose a system, as described above, that teaches all the limitations of the claim except for a coating. However, since Doneen et al. teach that saliva stimulation, at least in part, affects the time that oral fluid is transferred between the mouth and the biometric device (see column 6/lines 48-67), it would have been obvious to one of ordinary skill in the art at the time Applicant's invention was made to provide a system similar to that of Kuo as modified by Giuliani et al., Murayama and Doneen et al. with a saliva-stimulating coating to adjust the time that the oral fluid is transferred.

In regards to claim 55:

Since Doneen et al. suggest a single use lollipop-type oral device to thereby avoid the spread of an infection (see column 3/lines 59-61), Kuo suggests a multiple bioassay system (see column 6/lines 11-20 & 39-44), and Murayama discloses an interchangeable power or base unit, it would have been obvious to one of ordinary skill in the art at the time Applicant's invention was made to provide a system similar to that of Kuo as modified by Giuliani et al., Murayama and Doneen et al. with a plurality of single-use lollipop-type oral device to conduct multiple bioassays while avoiding the spread of an infection.

In regards to claim 57:

Since Doneen et al. and Kuo teach a means for inducing a physical change in a patient (i.e. saliva-stimulation) (see Doneen et al., column 5/lines 35-38 & abstract; see Kuo, column 9/lines 10-12 & abstract), it would have been obvious to one of ordinary skill in the art at the time Applicant's invention was made to provide a system similar to that of Kuo as modified by Giuliani et al., Murayama and Doneen et al. with a means, as claimed, since such a modification would serve the same purpose of stimulating saliva production.

5. ***Claims 8 & 60-61*** are rejected under 35 U.S.C. 103(a) as being unpatentable over Kuo in view of Giuliani et al., Murayama, Doneen et al. further in view of Lundell et al. (US 6,611,780).

Kuo as modified by Giuliani et al., Murayama and Doneen et al. disclose a system, as described above, that teaches all the limitations of the claim except for a cradle unit.

However, Lundell et al. disclose a system comprising a biometric device 10 including a base unit 11 that provides data processing and communication in addition to a cradle unit 12, which further produces data processing, communication and/or display; the system further comprising wireless transmission and programming of the biometric device; wherein the system further comprises an external instrument 34 capable of aiding and enhancing the utility of the system for downloading data from the biometric device, for logging or analysis, of providing power and/or control over the biometric device (see figs. 1A-B; column 1/lines 8-14 & 55-62; column 2/lines 10-31 & 50-67; column 3/lines 14-32; column 5/lines 43-48 & 56-60).

In regards to claim 8, since Lundell et al. and Kuo as modified by Giuliani et al., Murayama and Doneen et al. teach a system comprising a biometric device including a base unit for providing a medical diagnosis, it would have been obvious to one of ordinary skill in the art at the time Applicant's invention was made to provide a system similar to that of Kuo as modified by Giuliani et al., Murayama and Doneen et al. with a cradle unit similar to that of Lundell et al. in order to charge the biometric device and communicate biometric data therefrom (see Lundell et al., column 2/lines 50-67).

In regards to claim 60, it would have been obvious to one of ordinary skill in the art the time Applicant's invention was made to provide a system similar to that of Kuo as modified by Giuliani et al., Murayama and Doneen et al. with a step similar to that of Lundell et al. in order to remotely program information into the biometric device (see Lundell et al., column 5/lines 43-48).

In regards to claim 61, it would have been obvious to one ordinary skill in the art at the time Applicant's invention was made to provide a system similar to that of Kuo as modified by Giuliani et al., Murayama and Doneen et al. with an external instrument similar to that of Lundell et al. in order to remotely analyze user profiles in clinical situations, monitor and control use of the biometric device by particular patients, and remotely display and analyze the biometric data (see Lundell et al., column 3/lines 20-25; column 5/lines 43-48 & 56-60).

6. ***Claims 52-54*** are rejected under 35 U.S.C. 103(a) as being unpatentable over Kuo in view of Giuliani et al., Murayama, Doneen et al. further in view of Mink et al. (US 6,303,081).

Kuo as modified by Giuliani et al., Murayama and Doneen et al. disclose a system, as described above, that teaches all the limitations of the claim except for a stimulating coating.

However, Mink et al. disclose a system comprising a biometric device 18, an oral device (BP), and a stick D; wherein the oral device includes a coating to stimulate salivary action to aid the bioassay (see figs. 3-4; see abstract; see column 4/lines 14-24; column 17/lines 44-50).

Mink et al., Doneen et al., and Kuo as modified by Giuliani et al. and Murayama, teach a system for making a physiological oral test that includes an oral platform, a biometric device and handle as an integral element; moreover, Mink et al., Doneen et al. and Kuo teach a step for stimulating salivary action to thereby aid the bioassay (see Doneen et al., column 5/lines 35-38 & abstract; see Kuo, column 9/lines 10-12 & abstract; see Mink et al., column 4/lines 14-24; column 17/lines 44-50 & abstract); as such, it would have been obvious to one of ordinary skill in the art at the time Applicant's invention was made to provide a system similar to that of Kuo as modified by Giuliani et al., Murayama and Doneen et al. with a coating similar to that of Mink et al. in order to stimulate to production of saliva.

7. ***Claims 58-59*** are rejected under 35 U.S.C. 103(a) as being unpatentable over Kuo in view of Giuliani et al., Murayama, Doneen et al. further in view of Kawamura et al. (US 6,685,471).

Kuo as modified by Giuliani et al., Murayama and Doneen et al. disclose a system, as described above, that teaches all the limitations of the claim except for means for imaging tissue.

However, Kawamura et al. disclose a system comprising a biometric device 1 and an imaging device 12; wherein the imaging device is an endoscope (see fig. 4; see abstract; column 7/lines 14-50).

Since both Kawamura et al. and Kuo as modified by Giuliani et al., Murayama and Doneen et al. teach an electrically powered oral device, it would have been obvious to one of ordinary skill in the art at the time Applicant's invention was made to provide a system similar to that of Kuo as modified by Giuliani et al., Murayama and Doneen et al. with an imaging device similar to that of Kawamura et al. in order to enable a user to observe whether or not the oral device is in the desired location in the oral cavity (see Kawamura et al., column 1/lines 43-49).

Response to Arguments

8. Applicant's arguments filed May 30, 2007 have been considered but are moot in view of the new ground(s) of rejection.

Conclusion

9. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Rene Towa whose telephone number is (571) 272-8758. The examiner can normally be reached on M-F, 8:00-16:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Max Hindenburg can be reached on (571) 272-4726. The fax phone

number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/RTT/